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10/563,133	06/12/2006	Gyorgyi Vereczkeyne Donath	1060-0164PUS1	1179
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BIRCH STEWART KOLASCH & BIRCH			EXAMINER	
PO BOX 747			SOLOLA, TAOFTQ A	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1625	
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/563,133	Applicant(s) VERECZKEYNE DONATH ET AL.
	Examiner Taofiq A. Solola	Art Unit 1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 February 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 12-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 12-18 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 12-18 are pending in this application.

Claims 1-11 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. Halogenated solvents, ketones, protic solvents, ether- and ester-types solvents, and alkyl hydrocarbons are defined in the specification, page 7, by examples. However, "[e]xemplification is not an explicit definition." The specification must set forth the definition explicitly and clearly, with reasonable clarity, deliberateness and precision, *Teleflex Inc. v. Ficosa North Am Corp.*, 63 USPQ2d 1374, (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1854 (Fed. Cir. 2001).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 12, 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term halogenated solvents, ketones, protic solvents, ether and ester type solvents, and alkyl hydrocarbons are not defined in the claims so as to determine the metes and bounds of the claims. Also, the terms are not compound names but functional groups that are present in thousands of compounds, most of which are not applicable in the instant process.

Response to Argument

Applicant's arguments filed 2/4/08 have been fully considered but they are not persuasive. Applicant contends the claims are patentable as amended. This is not persuasive for reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-18, are rejected under 35 U.S.C. 103(a) as being unpatentable over Lifshitz-Liron et al., WO 03/051362 A2.

Applicant claims a process of making polymorph I of compound I, comprising dissolving the base in type A solvent, adding sulfuric acid in type A or B solvent, followed by type B solvent containing polymorph I of compound I (seeding) to form a precipitate of the product or cooling the mixture to zero. In preferred embodiments type A solvent is acetone or dichloromethane and type B is diethyl ether.

Determination of the scope and content of the prior art (MPEP 2141.01)

Lifshitz-Liron et al., teach a similar process wherein type A solvent is acetone or dichloromethane and type B is diethyl ether. The product is left to precipitate without seeding.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Lifshitz-Liron et al., is that applicant claims seeding the reaction mixture. Also, Lifshitz-Liron et al., do not teach using type B solvent to add sulphuric acid.

Finding of prima facie obviousness—rational and motivation (MPEP 2142.2413)

However, Lifshitz-Liron et al., teach acceleration of crystallization by seeding, which is well known in the art of crystallization. See page 24, line 1. Also, cooling the reaction mixture to zero is well known in the art of crystallization. Using type B solvent to add sulfuric acid is an obvious modification available to the preference of an artisan. Therefore, the instant invention is *prima facie* obvious from the teaching of Lifshitz-Liron et al. One of ordinary skill in the art would have known to seed or cool the reaction mixture at the time the invention was made. The motivation is from the teaching of Lifshitz-Liron et al., and because seeding or cooling reaction mixture are well known in the art of crystallization process.

Alternatively, given the teaching of Lifshitz-Liron et al., that the precipitate takes between 45 minutes to 8 hours, and seeding is applicable in the process. Given that that seeding and/or cooling are well known to accelerate crystallization procedures, it would have been obvious to try seeding and/or cooling at the time the invention was made.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation

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but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,____, 82 USPQ2d 1385, 1397 (2007).

Alternatively, given the common practice of using seeding and/or cooling in crystallization procedures and/or the teaching of the prior art, one of ordinary skill faced with the need to accelerate crystallization of the product would have known to use seeding and/or cooling, at the time the invention was made. "When a work is available in one field of endeavour, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technology is obvious unless its actual application is beyond his or her skill." "One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR Int. Co. v. Teleflex Inc*, 550 U.S. ____ , 82 USPQ2d 1385 (2007).

Alternatively, the instantly claimed process, seeding and/or cooling thereof are not applicant's invention. They are in the public domain prior to the time the instant invention was made. Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function it did no more than what they would have done separately. *In re Anderson*, 396 U.S. 57, 163 USPQ 673 (1969) cited in *KSR Int. Co. v. Teleflex Inc*, 550 U.S. ____ , 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result,

the combination is obvious. *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in KSR, *supra*. A patent for such combination "obviously withdraws what is already known into the field of its monopoly." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in KSR, *supra*.

Response to Argument

Applicant's arguments filed 2/4/08 have been fully considered but they are not persuasive. Applicant contends the compounds of the prior art are not as pure as in the instant. This is not persuasive for reasons set forth above. Applicant further argues that crystallization is a problematic process and that one of ordinary skill in the art would not have been motivated to prepare the instant polymorph. This is not persuasive because a problematic process does not mean it is not obvious and Lifshitz-Liron et al., are deemed people of ordinary skill who prepared the polymorph. In fact one of ordinary skill in the art of crystallization would have known to modify equipment and chemicals to obtain purer form of the crystals. See *Ex parte Conn and Norman*, 119 USPQ 388 (1956). Therefore, the instant process is no more than a selective combination of prior arts' teachings, done in a manner obvious to one of ordinary skill in the art, and there is no indication that the combination is such that would lead one of ordinary skill in the art to doubt the combination could not be made. *In re Mostovych*, 144 USPQ 38 (CCPA, 1964).

Specification

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. For examples, see page 3, paragraph 2, page 5, last 3 lines, page 13, last 3 lines and page 14, line 1.

The specification cites several patent applications, which are not incorporated by reference per the MPEP which states:

A mere reference to another application, publication or patent is not an incorporation of anything therein into the application containing such reference for the purpose of satisfying the requirement of 35 USC 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). Particular attention should be directed to the subject matter and the specific portions of the referenced document where the subject matter being incorporated may be found. MPEP 608.01(p).

If the document is a pending US application: prior to allowance of an application that incorporates essential material by reference to a pending US application, if the referenced application has not been published or issued as a patent, applicant is required to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating the amendment consists of the same material incorporated by reference in the referencing application. MPEP 608.01(p).

Applicant should note that incorporation of a foreign document, which is not published in English language, is not allowed.

The substitute specification filed must be accompanied by a statement that it contains no new matter.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

March 18, 2008